

October 1, 1998

The Honorable Michael A. Friedman
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Friedman:

This past Sunday, *The Washington Post* reported on a very disturbing violation of patient privacy by pharmacy benefit managers (see Robert O'Harrow, Jr. "Plans' Access to Pharmacy Data Raises Privacy Issues," *Washington Post*, September 27, 1998, page 1).

The article described the experience of Joan Kelly, a woman whose private and personal prescription information was accessed by a pharmacy benefit company, which in turn, used the information to inform her doctor that she would be enrolled into a "depression program," have her prescriptions for anti-depression medication monitored, and be sent "educational" material on depression. The problem, as it turns out, is that Mrs. Kelly was not suffering from any depression-related illness. Her doctor prescribed the medication to help her sleep. Mrs. Kelly had no way of knowing that by using her prescription-drug card, the protective armor of privacy among patient, doctor, and pharmacist had been pierced by the high-tech torpedo of her employer's pharmacy benefit manager (PBM), and potentially, her employer.

This story serves to underscore my concern that laws protecting the privacy of personal information are woefully inadequate -- be it consumer credit, personal financial, or sensitive medical information, most Americans are unprotected and unaware.

The General Accounting Office (GAO) conducted a review of mergers between PBMs and pharmaceutical manufacturers in 1995. While the review focused on the role of PBMs in the health care industry; the competitive ramifications of industry mergers; and the extent to which PBMs have given preference to their manufacturer partner's drugs; it was silent on the patient privacy issues that might be raised by such transactions.

Given the troubling revelations reported in the *Post* story, I believe the Food and Drug Administration should examine this issue to explore the privacy implications of the PBM role in the health care industry. To that end, I would appreciate your assistance and cooperation in responding to the following questions:

1. What is the nature and quantity of information collected by prescription benefit managers and what are their legal, ethical, and industry-accepted obligations for keeping that information confidential? Do PBMs have the right to collect and use such information? Who regulates the use and distribution of prescription information? What are the penalties for privacy violations?
2. How common is the practice of an employer requesting that a PBM review its prescription database and for what purposes are such requests made? Are the

pharmaceutical manufacturer partners of PBMs ever responsible for such a request? In what manner is data collected and shared with employers or pharmaceutical manufacturers?

3. Are doctors, pharmacists, and patients given any notification that personal prescription information is being collected about them? Are doctors, pharmacists, and patients asked to give their permission to PBMs prior to the collection of personal prescription information? If doctors, pharmacists, and patients are given notice that the information is being collected and/or asked their permission, are they also given the opportunity to refuse to have that information collected and distributed?
4. Does the potential exist for PBMs to use prescription information to target unknowing consumers for sales, marketing, or anti-competitive practices? Does the potential exist for employers to use the prescription information gathered by PBMs to discriminate against unsuspecting employees through dismissal or harassment?
5. And finally, what are the typical error rates in this type of data collection? What types of corrective actions can be taken when mistakes are identified by the PBMs or by doctors, pharmacists, or patients? What options are available to health care consumers to correct inaccurate records?

Thank you for your assistance and cooperation in responding to this inquiry. I request that a response be provided at your earliest convenience, but not later than October 30, 1998.

Sincerely,

Edward J. Markey